

From the INTERNATIONAL BUREAU

**PCT**

NOTIFICATION CONCERNING  
TRANSMITTAL OF COPY OF INTERNATIONAL  
PRELIMINARY REPORT ON PATENTABILITY  
(CHAPTER I OF THE PATENT COOPERATION  
TREATY)  
(PCT Rule 44bis.1(c))

To:

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Brisbane, QLD 4000  
AUSTRALIE

Date of mailing (*day/month/year*)  
27 April 2006 (27.04.2006)

Applicant's or agent's file reference  
FP20447-BJN

**IMPORTANT NOTICE**

International application No.  
PCT/AU2004/001399

International filing date (*day/month/year*)  
13 October 2004 (13.10.2004)

Priority date (*day/month/year*)  
13 October 2003 (13.10.2003)

Applicant

BIONOMICS LIMITED et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO  
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# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference FP20447-BJN	FOR FURTHER ACTION		See item 4 below
International application No. PCT/AU2004/001399	International filing date ( <i>day/month/year</i> ) 13 October 2004 (13.10.2004)	Priority date ( <i>day/month/year</i> ) 13 October 2003 (13.10.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant BIONOMICS LIMITED			

<p>1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 <i>bis</i>. I (a).</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.</p>	
<p>3. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I                      Basis of the report</p> <p><input type="checkbox"/> Box No. II                      Priority</p> <p><input checked="" type="checkbox"/> Box No. III                      Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV                      Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V                      Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI                      Certain documents cited</p> <p><input type="checkbox"/> Box No. VII                      Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII                      Certain observations on the international application</p>	
<p>4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).</p>	

<p>The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. +41 22 740 14 35</p> <p>Form PCT/IB/373 (January 2004)</p>	<p>Date of issuance of this report 18 April 2006 (18.04.2006)</p>
	<p>Authorized officer</p> <p>Dorothee Mülhausen</p> <p>Telephone No. +41 22 338 87 40</p>

# PATENT COOPERATION TREATY

From the:  
INTERNATIONAL SEARCHING AUTHORITY

REC'D 16 NOV 2004

WIPO PCT

To:

Griffith Hack  
GPO Box 3125  
BRISBANE QLD 4001

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing  
(day/month/year) 10 NOV 2004

Applicant's or agent's file reference  
BJN:MR:FP20447

FOR FURTHER ACTION  
See paragraph 2 below

International application No.  
PCT/AU2004/001399

International filing date (day/month/year)  
13 October 2004

Priority date (day/month/year)  
13 October 2003

International Patent Classification (IPC) or both national classification and IPC  
Int. Cl.<sup>7</sup> C12Q 1/68

Applicant  
BIONOMICS LIMITED et al

**1. This opinion contains indications relating to the following items:**

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

**2. FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

**3. For further details, see notes to Form PCT/ISA/220.**

Name and mailing address of the IPEA/AU  
AUSTRALIAN PATENT OFFICE  
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E-mail address: pct@ipaustalia.gov.au  
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WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/AU2004/001399

Box No. I      Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material  
☐ a sequence listing  
☐ table(s) related to the sequence listing
  - b. format of material  
☐ in written format  
☐ in computer readable form
  - c. time of filing/furnishing  
☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/AU2004/001399

**Box No. V**      **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims 11-13, 18-23 and 27	YES
	Claims 1-10, 14-17 and 24-26	NO
Inventive step (IS)	Claims	YES
	Claims 1-27	NO
Industrial applicability (IA)	Claims 1-27	YES
	Claims	NO

**2. Citations and explanations:**

The specification discloses the linkage between benign familial infantile seizures and mutations in the SCN2A gene. It also discloses that this information can be used in conjunction with existing information about the linkage between the KCNQ2 and KCNQ3 genes and benign familial neonatal seizures to distinguish between these different types of epilepsy.

The following documents identified in the International Search Report have been considered for the purposes of this report:

- D1    Heron et al (2002) The Lancet 360, 851-2
- D2    Mulley et al (2003) Current Opinion in Neurology 16, 171-6
- D3    WO 2003 008574

**Novelty and Inventive Step**

Berkovic et al (2004) is not discussed here because the citation was published after the priority date of the application.

Both D1 and D2 disclose methods of identifying individuals with BFNIS by amplifying regions of the SCN2A gene and identifying mutations in the gene following electrophoresis and sequencing. Each citation also discloses diagnosis of BFNIS by identifying mutations in the KCNQ2 and/or 3 genes. As such both citations fully disclose the methods of claims 1-10, 14-17 and 24-26, thereby depriving these claims of novelty and an inventive step. With respect to the remaining claims, which define other well known methods of identifying and characterising genetic mutations, these additional features are standard alternatives to the methods disclosed in the citations. As such, these claims lack an inventive step in light of each of the citations.

Although D3 also discloses methods of diagnosing epilepsies, including benign familial epilepsies by detecting mutations in the SCNA genes. The citation does not provide a direct link between BFNIS in particular and SCNA2. As such the citation represents background art that does not clearly impact on the novelty or inventive step of the claims.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

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**Box No. VIII** Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 8 is not fully supported by the description. The description focuses on detection of mutations in the SCN2A gene and correlating these mutations with BFNIS. Although the description also discusses mutations in the KCNQ2 and 3 genes, this information is disclosed in the context of the prior art and of diagnosis of BFNS and is distinguished from the applicant's invention, which relates to SCN2A and BFNIS.

In contrast to this, use of the term and/or in the claim results in a claim that may simply define a method of diagnosis by detecting mutations in KCNQ2 or 3 alone. As such the claim does not necessarily require use of the invention as disclosed in the specification.